

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

VMEKE AVERHART, etc.,

Plaintiff,

Case No. 3:09 oe 40028

-vs-

MEMORANDUM OPINION

ORTHO-MCNEIL PHARMACEUTICAL,  
INC., et al.,

Defendants.

KATZ, J.

Plaintiff B. Averhart, who was a minor when this case was filed, brought this action by her guardian against defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc., McKesson Corporation, and five hundred John Does. She alleges she was injured by using the transdermal birth control patch Ortho Evra®. Originally filed in the Southern District of Mississippi, the Judicial Panel on Multidistrict Litigation transferred the case to this Court. Before the Court now is Defendants' summary judgment motion and motion for judgment on the pleadings.

**I. Background**

Ortho Evra® is a hormone-based birth control medication delivered transdermally by a patch. (Memorandum, Doc. 21-10 at 2.) A user wears one patch per week on her skin for three weeks, wears no patch for the fourth week, then begins the cycle again. (*Id.*) To work transdermally, Ortho Evra® delivers a higher dosage—approximately 60% higher—of estrogen than oral contraceptives. (Package insert, Doc. 21-10 at 3–4.) “Increased estrogen exposure may increase the risk of adverse events including venous thromboembolism.” (*Id.* at 4.)

In 2008, Ms. Averhart, then 16, went to the Jackson County, Mississippi Health Department clinic seeking birth control. (Averhart Dep., Doc. 21-3 at 47.) She went alone, but

with her mother's permission. (Vmeke Averhart Dep., Doc. 21-6 at 15–16.) At the clinic, a family nurse practitioner and a nurse saw Ms. Averhart and, following an exam and discussion, offered her a choice of receiving birth control by a patch, a pill, or a shot. (Doc. 21-3 at 50–51.) Ms. Averhart says she chose the patch because: “I’m afraid of needles, to get shots. And with pills, I know you have to take them every day at the same time and I didn’t want to forget to take my pills.” (*Id.* at 51–52.) She was given a two-month sample of Ortho Evra®. (Plaintiff Fact Sheet, Doc. 21-2 at 20; Doc 21-3 at 225–35.)

Around three months later, Ms. Averhart suffered pain and swelling in both legs that rendered her unable to walk or dress herself. (Doc. 21-2 at 23.) Her mother took her to the hospital where she was admitted and diagnosed with bilateral deep vein thrombosis (DVT). (Doc. 21-2 at 23-24, 27; B. Averhart Dep., Doc. 21-3 at 23 – 24.)

## **II. Jurisdiction and Choice of Law**

Ms. Averhart originally filed this action in the United States District Court for the Southern District of Mississippi. Because Ms. Averhart is a citizen of Mississippi, Ortho-McNeil is a Delaware corporation with its principal place of business in New Jersey, and McKesson is a Delaware corporation with its principal place of business in California, and because the amount in controversy exceeds \$75,000, the district court had jurisdiction. 28 U.S.C. § 1332; (*see* Compl., Doc. 1 at ¶¶ 6, 9; Answer, Doc. 15 at ¶¶ 10, 15.) The Judicial Panel on Multidistrict Litigation consolidated this case with numerous others under MDL Number 1742 and assigned them to this Court pursuant to 28 U.S.C. § 1407. (*See* Conditional Transfer Order 80, Doc. 13.)

The parties agree Mississippi law applies.

## **III. Summary Judgment Motion**

Summary judgment is appropriate where “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (*quoting* Fed. R. Civ. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the

existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

"In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party." *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, "'at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter,'" *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, "[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact." *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment "is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried." *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

Ms. Averhart claims Defendants are liable because they failed to warn her of the dangers associated with taking Ortho Evra®. Defendants assert they are not liable because of Mississippi's learned intermediary doctrine.

#### **A. The Learned Intermediary Doctrine**

Defendants have moved for summary judgment based on Mississippi's Learned Intermediary Doctrine. The Learned Intermediary Doctrine provides a defense to drug manufacturers in failure to warn claims. *Wyeth Lab., Inc. v. Fortenberry*, 530 So.2d 688, 691

(Miss. 1988). The Learned Intermediary Doctrine precludes a manufacturer's liability where the manufacturer adequately warned the plaintiff's prescribing professionals, and where a different warning to the prescribers would have changed the prescribing decision. *Id.* at 691-92.<sup>1</sup> The Learned Intermediary Doctrine requires a manufacturer "to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* (quoting *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). Their duty to warn extends to physicians and not to laymen. *Id.* Consequently, the physician acts as a "learned intermediary" between the drug manufacturer and the patient because he "take[s] into account the propensities of the drug, as well as the susceptibilities of his patient." *Id.* On the other hand, "[i]f there is no physician in the role of 'learned intermediary' then the drug manufacturer has a duty to adequately warn the consumer." *Fortenberry*, 530 So.2d at 692.

Ms. Averhart says the learned intermediary doctrine does not absolve Defendants of liability in this matter for two reasons: first, a nurse practitioner and not a physician prescribed Ortho Evra® and, second, Defendants' warnings were inadequate to warn physicians.

#### **B. Lack of a Prescribing Physician**

A physician did not see Ms. Averhart at the clinic. When she arrived, Nurse's Aide Eva Heard saw Ms. Averhart and collected basic information. Then, Nurse Michael Rice collected her medical history, counseled her, and had her sign consent forms. Following that, Nurse Practitioner Wanda Dedeaux saw Ms. Averhart and prescribed Ortho Evra®. Nurse Rice then provided her

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The Mississippi legislature has codified that a product manufacturer is liable when the product "fail[s] to contain adequate warnings or instructions." Miss. Code Ann. § 11-1-63(a)(i)(2).

with samples of the drug. Ms. Averhart says that since NP Dedaux is not a physician, Defendants cannot invoke the learned intermediary doctrine.

Ms. Averhart argues Mississippi statutes only allow physicians to prescribe contraceptives to minors. Specifically, Miss. Code § 41-42-7 states that “[c]ontraceptive supplies and information may be furnished by physicians to any minor . . . who has the consent of his or her parent or legal guardian.” *See also* Miss. Code § 41-41-3 (listing who can consent on behalf of a minor to medical treatment “prescribed or directed by a duly licensed physician”). As such, she argues the learned intermediary doctrine is inapplicable to her case, in which a Nurse Practitioner prescribed her Ortho Evra®.

The Court disagrees with Ms. Averhart’s contention that Section 41-42-7 or Section 41-41-3 limits the authority to write contraceptive prescriptions for minors to just physicians. It says such contraceptives “may be furnished by physicians to any minor” but does not say they may not be furnished by a nurse practitioner. Ms. Averhart cannot demonstrate that NP Dedaux acted outside the law in furnishing her with Ortho Evra®. Moreover, Nurse Practitioners have the authority to write such prescriptions. Miss. Code § 73-15-20; Miss. Admin. Code § 30-18-2840:2.3; § 30-18-2840:2.4. This statute allows nurse practitioners to write prescriptions for most medication, and, most importantly, neither the administrative code nor the statute that enables it limits a Mississippi nurse practitioner’s ability to prescribe contraceptives to minors. Further, Ms. Averhart does not offer, and the Court does not find, any authority negating the learned intermediary doctrine’s application to instances where Nurse Practitioners prescribe the drug in question.

### **C. Adequacy of the Warning to the Learned Intermediary**

The learned intermediary doctrine shifts the recipient of product warnings from the patient to the intermediary (nurse practitioner in this case), but does not otherwise suspend a drug manufacturer's duty to warn; the manufacturer has a duty to adequately warn prescribers of potential consequences. Miss. Code § 11-1-63(a)(i)(2). Ms. Averhart says the warning provided by Defendants to NP Dedeaux was inadequate to properly communicate the drug's risk and allow her to exercise professional judgment on whether it was appropriate for Ms. Averhart. Generally, the adequacy of warnings—whether they are made to the consumer or a learned intermediary—is a question reserved for the jury. *Fortenberry*, 530 So.2d at 692. Nevertheless, courts can find as a matter of law that a warning was adequate if it specifically warns against the ultimate adverse effect. *Id.* at 692–93.

Ms. Averhart specifically says Defendants did not ensure NP Dedeaux received their updated warnings. She points to NP Dedeaux's lack of recollection of receiving any particular mailings, including a Dear Health Care Provider letter, from Defendants. (Dedeaux Dep., Doc. 21-5 at 27, 94–95.) Nevertheless, NP Dedeaux acknowledged she “read the package insert and the detailed patient labeling for ORTHO EVRA patch,” and that she was “aware that the risks of using the ORTHO EVRA patch include deep vein thrombosis, pulmonary embolism, ischemic strokes, myocardial infarctions or heart attacks and other risks.” (Doc. 21-5 at 47.) To prevail on this point, Ms. Averhart would have to show more than just the fact NP Dedeaux cannot specifically recall this letter. In fact, even if Ms. Averhart could conclusively show NP Dedeaux did not receive the letter, that still may not be enough; to survive summary judgment, Ms. Averhart needs to point to some evidence indicating Defendants did not adequately warn NP Dedeaux.

Since NP Dedeaux testified she understood that Ortho Evra® created a risk of the very thing that happened to Ms. Averhart, Defendants have shown they warned the learned intermediary (through whatever means) adequately. *See Fortenberry*, 530 So.2d at 693 (finding a warning adequate as a matter of law where it warned of the potential for the condition that befell the plaintiff); *Cather v. Catheter Tech. Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991) (“A warning may be held adequate as a matter of law where the adverse effect that was ultimately visited upon the patient was one that the manufacturer specifically warned against.”); *cf.* Miss. Code § 11-1-63(d) (“[T]he manufacturer . . . shall not be liable if the claimant . . . “had knowledge of a condition of the product that was inconsistent with his safety.”). Ms. Averhart points to no evidence to the contrary.

#### **D. Adequacy of the Warning to Ms. Averhart**

Ms. Averhart says the warning she received from the Jackson County Health Department about the dangers of taking Ortho Evra® was inadequate because she was not advised of the dangers of the drug by the prescribing nurse practitioner, the clinic’s consent form was inadequate, and she was not given a package insert. These arguments are immaterial because Defendants discharged their duty by warning the learned intermediary. *Fortenberry*, 530 So.2d at 691 (“If the language of the warning [to the learned intermediary] is adequate then the drug manufacturer ordinarily is freed from liability.” (quotation marks and citation omitted)).

#### **IV. Judgment on the Pleadings**

Defendants move for judgment on the pleadings as to all remaining claims beyond failure to warn.



A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir.2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim “that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court must accept as true all of the non-movant’s factual allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2013). The complaint “need not contain ‘detailed’ factual allegations, [but] its ‘factual allegations must be enough to raise a right to relief above the speculative level . . . .’” *Ass’n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. *Twombly*, 550 U.S. at 555 (holding that a complaint must contain more than “a formulaic recitation of the elements of the cause of action”).

Defendants move for Rule 12(c) judgment on the pleadings on grounds that “plaintiff’s alternative theories of recovery – beyond failure to warn – are couched in terms of conclusory allegations.” (Memo., Doc. 21-10 at 21.) Plaintiff’s opposition brief does not respond to Defendants’ Rule 12(c) arguments. The Court nevertheless reviews the sufficiency of Plaintiff’s complaint to determine whether Defendants are entitled to judgment as a matter of law. *See Paskavan*, 946 F.2d at 1235 (Rule 12(c) movant must be entitled to judgment as a matter of law).

Here, Plaintiff’s complaint pleads sufficient factual matter to state plausible causes of action and to put Defendants on notice as to the nature thereof. *See Twombly*, 550 U.S. at 554-55, 570 (interpreting Fed. R. Civ. P. 8(a)’s pleading standard). Further, Plaintiff pleads her fraud claim with particularity as required by Fed. R. Civ. P. 9(b). (*See Compl.*, Doc. 21-4 at PageID #

219) (enumerating a list of Defendants' allegedly fraudulent actions). As such, Defendants' motion for judgment on the pleadings will be denied.

**V. Conclusion**

For the reasons stated herein, Defendants' motion for summary judgment as to Ms. Averhart's failure-to-warn claims is granted, and Defendants' motion for judgment on the pleadings as to Plaintiff's remaining state law claims is denied. (Doc. 21.)

IT IS SO ORDERED.

s/ David A. Katz  
DAVID A. KATZ  
U. S. DISTRICT JUDGE